

REMARKS

Claims 1, 3, 7, 9-16, and 25 are pending in this application. Claims 1, 3, 7, and 9-16 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 102(e) for anticipation by, and under 35 U.S.C. § 103(a) for obviousness over, Constantz et al. (U.S. Patent No. 5,782,971; hereinafter “Constantz I”). Claim 25 is rejected under 35 U.S.C. § 102(b) for anticipation by Brown et al. (RE 33,221; hereinafter “Brown”). Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 103(a) for obviousness over Simkiss et al. (WO 94/02412; hereinafter “Simkiss”) alone, and over Simkiss in combination with Brown. Finally, claims 1, 3, 7, 9-16, and 25 are rejected for obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,214,368 (hereinafter “the ‘368 patent”), claims 1-2 of U.S. Patent No. 6,132,463 (hereinafter “the ‘463 patent”), claims 1-21 of U.S. Patent No. 6,027,742 (hereinafter “the ‘742 patent”), and claims 1-9 of U.S. Patent No. 6,331,312 (hereinafter “the ‘312 patent”). By this reply, Applicants amend claims 1 and 25 and address each of the Examiner’s rejections.

Rejections over 35 U.S.C. § 112, second paragraph

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness for reciting “as shown in Figure 3c.” Applicants have amended claim 1 to exclude this phrase. This rejection may now be withdrawn.

Rejections over 35 U.S.C. § 102(e)

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 102(e), as anticipated by or, in

the alternative, under 35 U.S.C. § 103(a) as obvious over, Constantz I. Applicants respectfully traverse the rejection.

The teachings of Constantz I cited by the Examiner are not prior art. For Constantz I to constitute prior art it must have a filing date earlier than the effective filing date of the present application. MPEP § 706.02(a); 35 U.S.C. § 102(e). The present application was filed on October 16, 1996 and has an earlier priority date of May 19, 1995. The filing date of Constantz I is July 21, 1998, which is after the filing date of the present application. Although Constantz I claims priority from earlier applications that were filed before July 21, 1998, those applications do not contain the pertinent teachings relied upon by the Examiner.

Constantz I is a continuation-in-part application of U.S. Serial No. 07/963,481, filed on October 16, 1992, now U.S. Patent No. 5,962,028 (hereinafter “Constantz II”). The Examiner relies on Constantz I for its disclosure of a “flowable amorphous calcium phosphate (ACP) composition capable of setting in vivo (endothermic process) into a shaped product. The paste contains in addition to ACP, a monocalcium phosphate (acidic calcium phosphate), and a liquid (sterile water). See column 4, lines 5-52 and column 5, lines 45-55.” (Office Action, p. 3.) This disclosure is absent from Constantz II, which only discloses “[c]ompositions comprised of dahllite, analogs thereof, or otherwise carbonate-substituted forms of hydroxyapatite (dahllite-like compositions)” (col. 4, lines 29-36). Since the disclosure of Constantz I cited by the Examiner does not predate the effective filing date of the present application, the disclosure of Constantz I does not constitute prior art and cannot be relied upon by the Examiner in issuing a rejection under 35 U.S.C. § 102(e). Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

Rejections over 35 U.S.C. § 102(b)

Claim 25 is rejected under 35 U.S.C. § 102(b) over Brown. The Examiner states that “Brown et al disclose...dental restorative cement pastes...The composition is a mixture of two sparingly soluble calcium phosphates and a dilute aqueous solution. The combination hardens into dental cement when contacted with living tissue.” (Office Action, p. 4.) Applicants have amended claim 25 to clarify that the paste applied to the prosthesis hardens to form a poorly crystalline apatitic (PCA) calcium phosphate. Brown does not teach or suggest a method for embedding a prosthetic device by applying to a surface of the prosthesis a paste that hardens to a PCA calcium phosphate, as is recited in present claim 25. Thus, this rejection may now be withdrawn.

Brown discloses dental remineralizers and dental cements prepared by reacting tetracalcium phosphate (“TTCP”) with a specially selected second calcium phosphate to form crystalline hydroxyapatite (“HA”; see col. 7, lines 1-9). Brown specifies that the calcium phosphate components are selected to form a cement that sets to form stoichiometric (crystalline) hydroxyapatite (HA), not a PCA calcium phosphate, as is recited in present claim 25 (see Brown, col.3, lines 36-60 and col. 6, line 51 to col. 7, line 3). Because there is no teaching or suggestion in Brown to select calcium phosphate components so as to provide a cement that sets to form a PCA calcium phosphate, Brown fails to teach or suggest all of the limitations of present claim 25. This rejection should now be withdrawn.

Rejections over 35 U.S.C. § 103(a)

Simkiss

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 103(a) for obviousness over Simkiss. The Examiner states:

Simkiss et al. teach an amorphous calcium phosphate that hardens to form bone in vivo...Simkiss also teaches the ability to modify the transformation rates when the material is exposed to body fluid, by including crystallization inhibitors...A slow mechanism is taught...[and] it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Simkiss and formulate a fast-setting precursor material...[I]t is the Examiner's position that Simkiss suggests the instant invention since clearly as discussed above, Simkiss not only provides motivation when to use a slow setting material versus a fast setting material but discloses that crystallization inhibitors and their concentrations modify the hardening rate. Therefore, the instant invention is viewed as prima facie obvious."

Office Action, pp. 6-8. Applicants respectfully traverse this rejection.

Simkiss describes preparing a hydroxyapatite composition, not a poorly crystalline apatitic (PCA) calcium phosphate. Simkiss prepares amorphous calcium phosphate with "calcium and phosphate ions as primary constituents together with inhibitor components (notably magnesium and/or pyrophosphate ions) which inhibit its transformation to a crystalline form (generally based on hydroxyapatite)" (see p. 2, line 33, through p. 3, line 2). Simkiss further discloses that leaching of the inhibitor components promotes the transformation of the amorphous calcium phosphate composition into crystalline hydroxyapatite (see p. 3, lines 2-6). Because Simkiss fails to teach or suggest the preparation of a PCA calcium phosphate for use in treating a bone defect or embedding a prosthesis, as is recited in present claims 1 and 25, and claims dependent therefrom, Simkiss fails to teach or suggest each and every limitation of these claims. The rejection of claims 1, 3, 7, 9-16, and 25 under 35 U.S.C. § 103(a) should be

withdrawn.

Simkiss and Brown

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 103(a) for obviousness over

Simkiss in combination with Brown. The Examiner states:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Simkiss et al. and Brown et al. and manipulate Simkiss's formulation to yield a fast-setting precursor material. One would be motivated since Brown et al. also teach a calcium phosphate injectable composition that has setting capabilities at physiological temperatures. Further, Brown provides guidance on how to manipulate the setting condition by changing the amount of hydroxyapatite, adding crystal modifiers such as magnesium, phosphonates, and citrates, which [are] also taught by Simkiss for the same purpose of manipulating setting time. Therefore, it can be seen that manipulation of setting times is a conventional practice done in the art at the time the invention was made. Lastly, one would be motivated to manipulate the parameters of the prior art depending on the intended use of the implant and treatment plan as taught by both Simkiss and Brown et al.

(Office Action., p. 10.) Applicants respectfully disagree that the method of claims 1, 3, 7, 9-16, and 25 is obvious over Simkiss and Brown.

The M.P.E.P. § 2143.03 states:

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.
In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

As is discussed above, both Simkiss and Brown disclose the preparation of a crystalline hydroxyapatite material; neither discloses the preparation of a poorly crystalline apatitic (PCA) calcium phosphate. Because Simkiss and Brown fail to teach or suggest all of the limitations of present claims 1 and 25, and claims dependent therefrom, the rejection of claims 1, 3, 7, 9-16,

and 25 under 35 U.S.C. § 103(a) for obviousness over Simkiss in combination with Brown should be withdrawn.

Constantz I

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 103(a) for obviousness over Constantz I. As is discussed above, Constantz I is not prior art to the present application. This rejection may now be withdrawn.

Obviousness-type Double Patenting Rejection

The Examiner rejects claims 1, 3, 7, 9-16, and 25 for obviousness-type double patenting over claims 1-14 of the '368 patent, claims 1-2 of '463 patent, claims 1-21 of the '742 patent, and claims 1-9 of the '312 patent. Applicants acknowledge the Examiner's withdrawal of the rejection of claims 1, 3, 7, 9-16, and 25 over claims 13-27 of U.S. Patent No. 6,287,341. In the event the pending claims are found to be otherwise allowable, Applicants will consider the appropriateness of filing a terminal disclaimer to overcome this rejection.

CONCLUSION

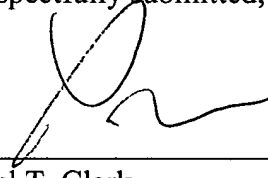
In view of the above remarks, Applicants respectfully submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including April 4, 2005, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

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Respectfully submitted,



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